UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TED DAVISON, WILLIAM GOULD, AND RAY LENCI, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, vs. VENTRUS BIOSCIENCES, INC., DR. RUSSELL H. ELLISON, and DAVID J. BARRETT, Defendants.	Index No.: 13 CIV 3119-RMB

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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I. PRELIMINARY STATEMENT

The Consolidated Amended Class Action Complaint ("CAC") is a classic case of investors who are eager to "expect to see returns on their investment" (CAC, ¶ 9), but are unwilling to bear the risks of a biopharmaceutical company trying to bring a drug to market. Ventrus' lead drug candidate, iferanserin ("VEN 309"), showed promise as a topical treatment for hemorrhoids. Defendants had reason to be optimistic about the drug's potential – a number of human clinical trials showed VEN 309 was effective in reducing (and in many cases, eliminating) the symptoms of hemorrhoids. On the basis of these results – and in consultation with the U.S. Food and Drug Administration ("FDA") – Ventrus initiated a "pivotal" Phase III trial. While the trial was ongoing, defendants repeatedly warned investors that VEN 309's favorable results in earlier trials might not be replicated in the Phase III trial. Unfortunately, as warned, the Phase III trial failed to meet its efficacy endpoints. Ventrus promptly disclosed the disappointing results and terminated the VEN 309 program. Ventrus' stock price then fell, and this lawsuit followed.

Plaintiffs' core theory is that defendants knowingly misled investors by making optimistic public statements about VEN 309. However, it is not disputed that: (1) defendants fully and accurately disclosed all of VEN 309's clinical trial results, including a Phase IIb trial that demonstrated statistically significant improvements using the same efficacy endpoints that were the subject of the more expansive Phase III trial; (2) Ventrus spent over $36 million on the VEN 309 clinical trial program; and (3) defendants increased their own Ventrus holdings by over 103% during the purported class period, putting themselves at the same risk as Ventrus' other investors. In view of these indisputable facts, the CAC lacks plausibility and, in any event, does not come close to meeting the heightened pleading standards of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA").

Failure to Allege Scienter: Entirely lacking from the CAC are any allegations of scienter – *i.e.*, facts sufficient to show a "strong inference" that defendants knew in advance that the Phase III trial would fail. This lack of allegations is not surprising given what actually occurred. As noted above, defendants significantly ***increased*** their own personal stakes in Ventrus during the class period, sold ***none of their own shares or vested options*** during the class period, and directed the vast majority of Ventrus' resources to the VEN 309 program – only to have their investment wiped out by the Phase III trial results. The CAC offers no reason why defendants would knowingly commit such economic self-destruction.

The CAC also offers no "strong circumstantial evidence of conscious misbehavior," such as a contemporaneous document, email, internal dispute or disagreement, or communication from the FDA, that calls into question defendants' optimism about the VEN 309 program or otherwise shows an "extreme departure from standards of ordinary care." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001). The CAC's inclusion of allegations from three Confidential Witnesses ("CWs") exemplifies this defect. Indeed, none of the CWs are alleged to have had any discussions with defendants about VEN 309, two CWs did not even work for Ventrus, and the other CW left Ventrus nearly two years before the class period began.

Failure to Allege Any False Statements: The CAC also fails to allege any false statement by any defendant. While the CAC quotes liberally from public statements and SEC filings, it fails to identify a single instance in which any reported fact is demonstrably false or inaccurate. Indeed, plaintiffs do not take issue with defendants' reporting of the earlier VEN 309 trial results or contend that those results were misrepresented. Moreover, defendants' optimistic forward-looking statements about VEN 309's future prospects are not actionable because they were accompanied by repeated and detailed risks that the Phase III trial might fail.

In the end, the CAC does not state a viable theory of fraud. It relies on 20-20 hindsight and the conclusory supposition that, because VEN 309 had disappointing Phase III trial results, any optimistic statements made in anticipation of those results must have been fraudulent. The securities laws require much more. The CAC should be dismissed with prejudice.

II. BACKGROUND FACTS

A. The Parties

Plaintiffs are individual Ventrus stockholders,[1] who seek to represent a class of all persons who purchased Ventrus stock between December 17, 2010 and June 25, 2012 (the "Class Period").[2] (CAC, ¶ 1.)

Defendant Ventrus is a New York biopharmaceutical company "focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence." (*Id.* at ¶¶ 6, 28.) Individual defendants Dr. Russell Ellison and David Barrett are, and were during the Class Period, members of Ventrus' management team. (*Id.* at ¶¶ 29-30.) Mr. Barrett is not alleged to have made any false or misleading statement. (*Id.* at ¶ 30.)

B. The Process for Testing and Approving New Drugs

To market a drug in the United States, developers must first obtain FDA approval. An FDA regulation provides for a three-phase clinical investigation of a proposed new drug in humans, with each phase involving increasingly larger patient pools. *See* 21 C.F.R. § 312.21. Phase I trials test the safety, dosage tolerance, and other properties of the drug. During Phase II trials, researchers test the drug in a limited patient population – "usually involving no more than

[1] Despite the PSLRA's clear preference for institutional investors (*see Malasky v. IAC/Interactivecorp*, 2004 WL 2980085, at *4 (S.D.N.Y. Dec. 21, 2004)), not one institutional investor filed a lawsuit or sought appointment as lead plaintiff. (*See* Dkt. Nos. 15, 18, 20, 31)

[2] Defendants reserve the right to oppose class certification.

several hundred subjects" – to gather information about efficacy, optimal dosage levels, adverse effects, and safety risks. *Abely v. Aeterna Zentaris, Inc.*, 2013 WL 2399869, at *2 (S.D.N.Y. May 29, 2013) (quoting 21 C.F.R. § 312.21(b)). Phase III trials are often referred to as the "pivotal" studies to "gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug" and usually include "several hundred to several thousand subjects." 21 C.F.R. § 312.21(c).

The FDA approval process is fraught with uncertainty. Only 10-16% of new drugs successfully pass through all phases of the FDA approval process. *See* J.A. DiMasi, *Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs*, 87 Clinical Pharmacology & Therapeutics 272, 273-74 (2010). Emphasizing this uncertainty, Ventrus repeatedly cautioned investors that its products were "subject to the risks of failure and delay inherent in the development of new pharmaceutical products" and that its "research and development efforts might not result in any commercially viable products." (Exh. A at 10.)[3] Ventrus also disclosed numerous risks specific to VEN 309. (*See* Section IV.B.4., *infra*.)

C. VEN 309

VEN 309: VEN 309 is a new chemical entity for the topical treatment of hemorrhoids. (CAC, ¶ 38.) By limiting activity in a serotonin receptor (5-HT2A), VEN 309 improves blood flow out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. (*Id.* at ¶ 34.) Ventrus licensed VEN 309 from Sam Amer & Co., Inc ("Amer") in March 2008 and acquired all rights and title to the drug in November 2011. (*Id.* at ¶¶ 8, 71;

[3] All "Exh." references are to exhibits attached to the Declaration of Ryan E. Blair, filed concurrently herewith. When ruling on a motion to dismiss, the Court "may consider . . . documents incorporated into the complaint by reference [and] legally required public disclosure documents filed with the SEC . . . ." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). (*See also* Request for Judicial Notice, filed concurrently herewith.).

Exhs. A at 6, 23, B at 35.) Ventrus spent over $36 million on the VEN 309 program, six times more than it spent on its other drug candidates. (CAC, ¶ 104; Exhs. C at 74, S at 258.)

The Phase IIb Trial: Between 1993 and 2003, Amer and one of its prior licensees – Tsumura Company – conducted seven clinical trials for VEN 309 involving 359 patients. (Exh. A at 6, 24; CAC, ¶¶ 38, 42.) Of these trials, the CAC focuses on a Phase IIb trial sponsored by Amer and conducted in Germany in 2003. (*See, e.g.*, *id.* at ¶¶ 13, 48, 50, *etc.*) The CAC does not dispute that the trial results showed statistically significant ($p < 0.05$)[4] reductions in key efficacy endpoints, including bleeding, itching, and pain, with no serious adverse events. (*See, e.g.*, CAC, ¶ 73; Exh. A at 6.) The CAC's challenge to the Phase IIb trial is limited to its purported "small" sample size (CAC, ¶ 13), but plaintiffs ignore that Ventrus repeatedly disclosed the 121-patient sample size to the public (*see, e.g.*, Exhs. A at 6, C at 53, D at 103).

The Phase III Trial: As part of an "end-of-Phase II" meeting with the FDA in February 2008, Ventrus and the FDA initially agreed that the primary endpoint for any Phase III clinical trials would be "time to the cessation of bleeding." (Exh. A at 6.) Ventrus and the FDA discussed a possible Special Protocol Assessment ("SPA"),[5] a voluntary process by which a drug sponsor, if it so chooses, can obtain FDA approval of its clinical trial protocol in advance. (CAC, ¶ 44; Exh. F at 117-18.) As the CAC concedes, "***completing an SPA has nothing to do with approval of the drug***, but rather that the FDA will simply accept the study as valid

[4] "Statistically significant" means that a given result is unlikely to have occurred by random chance or due to factors outside the control of a study. Statistical significance is expressed as a "p-value," which represents a probability that a particular hypothesis tested by a trial happened by chance. Statistical significance consisting of a p-value of less than 0.05 has traditionally been considered convincing evidence by the FDA. *See* R. Chin & B. Lee, *Principles and Practice of Clinical Trial Medicine*, 130 (1st ed. 1996).

[5] An ongoing "give and take" with the FDA is common for a pharmaceutical company and is "the essence of the . . . license application process." *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995).

protocol." (CAC, ¶ 14 (emphasis added).) In other words, whether or not there is an SPA for a drug sponsor's clinical trial, there can be no assurance about the efficacy or safety results of that particular trial.

Here, although Ventrus did not formally complete the SPA process, it had numerous discussions with the FDA and, on June 22, 2011, announced that it had agreed to implement all of the FDA's proposed changes into its VEN 309 Phase III clinical trial protocol. (*Id.* at ¶ 55.) As a practical matter, Ventrus' adoption of the FDA's proposed changes made further pursuit of an SPA unnecessary and allowed Ventrus to start its Phase III trial "as planned" and without risk of further administrative delay. (*Id.* at ¶¶ 55, 59, 61; Exhs. F at 124, G at 132).[6]

The double-blind, 600-patient Phase III trial began in July 2011, with its primary efficacy endpoint being "the cessation of bleeding by the end of Day 7 that persists for the remainder of the treatment period (through Day 14)." (Exh. H at 133.) Secondary efficacy endpoints included cessation of pain and itching for the same time period. (*Id.* at 134.) These same endpoints were previously examined in a *post hoc* analysis of the Phase IIb trial, which showed VEN 309 had a statistically significant impact on the cessation of bleeding by Day 7 through Day 14 when compared to placebo ($p < 0.0001$), as well as the cessation of pain ($p = 0.032$) and itching ($p = .034$). (CAC, ¶ 75; Exh. E at 112.) This *post hoc* analysis was confirmed by and published in a leading peer-reviewed journal, *Clinical Therapeutics*, in January 2012. (*Id.*). Ventrus did not conduct the Phase III trial itself; rather, Ventrus contracted all work to contract research organizations ("CROs"). (CAC, ¶ 103.)

[6] Ventrus explained that "[g]iven the substantial progress we have made with the FDA in this [SPA] process, we have decided to proceed directly implementing our protocol with all FDA recommended changes without further pursuing the SPA." (CAC, ¶ 55.) Importantly, nowhere in the CAC do plaintiffs challenge the structure or design of the Phase III clinical trial, only the outcome.

Ventrus announced the results of the Phase III trial on June 25, 2012. (CAC, ¶ 89.) The CAC does not provide any evidence that defendants had advance knowledge of the trial results, and there is no document or record of any kind and no statement by any CW that comes close to suggesting that defendants were proceeding in bad faith or had reason to know that the Phase III trial would fail. As such, the results of the Phase III trial were disappointing to defendants and shareholders alike. Ventrus announced that based on the Phase III trial results, including the failure to meet the primary and secondary efficacy endpoints,[7] it was discontinuing the VEN 309 program. (*Id.* at ¶¶ 90-92.) Despite Ventrus' repeated warnings to investors that the VEN 309 program might not succeed, Ventrus' stock price dropped and this lawsuit followed.

III. APPLICABLE LEGAL STANDARDS

A. Motions to Dismiss Under Fed. R. Civ. P. 12(b)(6)

The Court must dismiss a complaint under Fed. R. Civ. P. 12(b)(6) where it fails to allege facts sufficient to "plausibly" state a claim for relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). While courts must accept factual allegations in a complaint as true, any "legal conclusions, deductions, or opinions couched as factual allegations are not given a presumption of truthfulness." *Gmurzynska v. Hutton*, 257 F. Supp. 2d 621, 625-26 (S.D.N.Y. 2003) (citation omitted); *see also Jones v. Ocwen Fed. Bank*, 147 F. Supp. 2d 219, 224 (S.D.N.Y. 2001) ("Individual allegations . . . that are so baldly conclusory that they fail to give notice of the basic events and circumstances of which the plaintiff complains, are meaningless as a practical matter and as a matter of law are insufficient to state a claim."). Moreover, if the documents that form

[7] The CAC grossly misstates the results of the Phase III trial by claiming that "every single participant in the VEN 309 Phase III trials . . .fail[ed] to meet the endpoints for improved bleeding, itching, and pain assess in the trials." (CAC, ¶ 89.) In fact, Ventrus disclosed that the Phase III trial "failed to demonstrate an improvement for therapy, in either treatment arm, ***over placebo*** for the primary and secondary endpoints." (*Id.* at ¶ 90 (emphasis added).)

the basis of plaintiffs' claims contradict the allegations in the CAC, "the documents control." *Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000).

B. Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5

To state a claim under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, a plaintiff must allege: (1) a misstatement or omission, (2) of material fact, (3) made with scienter, (4) on which they relied, (5) proximately causing injury. *Lattanzio v. Deloitte & Touche LLP*, 476 F.3d 147, 153 (2d Cir. 2007). Because fraud allegations harm livelihoods, there is a heightened pleading standard, requiring a plaintiff "to state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Further, the PSLRA heightened Rule 9(b)'s "particularity" requirement by imposing much more stringent requirements for pleading scienter and falsity. *See* 15 U.S.C. § 78u-4(b)(1)-(3).

Scienter. A complaint must "state with particularity facts giving rise to a strong inference" that each defendant possessed an intent to defraud investors or acted with recklessness. 15 U.S.C. § 78u-4(b)(2); *ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009).[8] Moreover, a complaint will survive a motion to dismiss only "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged," weighing all "plausible nonculpable explanations for the defendant's conduct" against "inferences favoring the plaintiff." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007); *Slayton v. Am. Express*, 604 F.3d 758, 775 (2d Cir. 2010) (requiring courts to make

[8] Dr. Ellison and Mr. Barrett cannot be liable for the false statements found in the CAC on a "group-pleading" theory. *Ross v. Lloyds Banking Grp., PLC*, 2012 U.S. Dist. LEXIS 148984, at *30 (S.D.N.Y. Oct. 16, 2012) ("Scienter may not be alleged through group pleading."). Rather, plaintiffs must plead specific facts showing *with particularity* that each individual defendant knew about the alleged falsity when the misrepresentation was made. *See* 15 U.S.C. § 78u-4(b)(2). As shown below, the CAC does not contain a scrap of evidence that Dr. Ellison or Mr. Barrett knew a single statement was false when made.

"a practical judgment about whether, accepting the whole factual picture . . . it is at least as likely as not that defendants acted with scienter").

Falsity. The PSLRA requires a plaintiff to identify specifically each statement alleged to have been false and to state the reasons demonstrating why the statement was false when made. *In re MRU Holdings Sec. Litig.*, 769 F. Supp. 2d 500, 508 (S.D.N.Y. 2011) (citation omitted). If a plaintiff claims a defendant omitted a material fact, it must show that the defendant had a duty to disclose the omitted information. *Basic v. Levinson*, 485 U.S. 224, 239 n.17 (1988). Rule 10b-5 does not require the disclosure of all material information. *See Matrixx v. Siracusano*, 131 S. Ct. 1309, 1321 (2011). Rather, "[d]islcosure is required . . . only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013) (citations omitted).

IV. PLAINTIFFS' RULE 10B-5 CLAIM MUST BE DISMISSED

A. The CAC Fails to Allege Facts Giving Rise to a Strong Inference of Scienter

In this Circuit, "scienter can be established by alleging facts to show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198. The CAC's scienter allegations fail under either theory.

1. The CAC Does Not Sufficiently Allege Motive

"In order to raise a strong inference of scienter through 'motive and opportunity' to defraud, [p]laintiffs must allege that [defendants] ***benefitted in some concrete and personal way*** from the purported fraud." *Id.* at 198 (emphasis added). Motive is usually evidenced by a showing that defendants sold their own shares, in suspicious timing or amounts, at a profit after making the alleged misrepresentation. *Id.*; *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp.

2d 261, 272 (S.D.N.Y. 2009) (dismissing complaint for lack of scienter where there was no "allegation that the timing or amounts of the [stock sales] was unusual or suspicious").

Here, the CAC does not allege that Dr. Ellison or Mr. Barrett sold a single share of Ventrus stock. To the contrary, together they ***increased their personal Ventrus holdings by 103% during the Class Period***, and then lost over $4.3 million in the value of their holdings by the end of the Class Period. (Exh. I at 137; CAC, ¶ 93.) These stark facts belie any notion that they had a financial motive to commit fraud or that they benefited in any personal way. In fact, they compel "the opposite inference." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 885 (9th Cir. 2012). Courts in this Circuit have repeatedly held that increasing one's stock holdings during the class period is sufficient to defeat any claim of scienter based on motive. *See, e.g.*, *MRU Holdings*, 769 F. Supp. 2d at 516 ("Individual Defendants' purchases of [company] stock during the [c]lass [p]eriod signals only confidence in the future of th[e] company." (citation omitted); *In re Regeneron Pharms., Inc. Sec. Litig.*, 2005 WL 225288, at *22 (S.D.N.Y. Feb. 1, 2005) ("It is well settled that such an action – i.e., the purchase of additional company shares during the class period – is inconsistent with an intent to commit fraud."); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004).

Lacking a strong theory of motive or personal gain, the CAC relies on a standard refrain of possible motives that could be said to apply to any public company or its officers, including: (1) Ventrus needed cash to finance the development of its licensed drugs (CAC, ¶ 9); (2) Ventrus raised cash through an initial public offering ("IPO") and two secondary offerings (*id.* at ¶¶ 11, 15); (3) Dr. Ellison and Mr. Barrett received annual salaries, stock options, and bonuses based, in part, on Ventrus' market capitalization (*id.* at ¶¶ 29-30). If these generic allegations sufficed under the securities laws to establish motive, then scienter could be established at any public

company that sought to raise capital or incentivize its management. For this reason, the Second Circuit held in *ECA* that these types of motives, "common to most corporate executives," are insufficient to plead scienter. 553 F.3d at 198. *All* companies need to raise capital, especially biopharmaceutical companies whose products have yet to be commercialized and require funds for further development. Such a routine corporate endeavor does not set Ventrus apart from any other company. *See In re Cross Media Mktg. Corp. Sec. Litig.*, 314 F. Supp. 2d 256, 265 (S.D.N.Y. 2004) (holding that allegations that defendants were motivated by a desire to raise capital or benefited by raising capital are insufficient to establish motive and opportunity) (citing cases). Similarly, "executive compensation, including stock options and bonuses . . . based partly on the executive's success in achieving corporate goals" is such common practice that no inference of scienter can be drawn "merely because a defedant's compensation was based in part on such successes." *Rigel*, 697 F.3d at 884; *Kalnit*, 264 F.3d at 139 ("Motives that are generally possessed by most corporate directors and officers do not suffice."). In short, the CAC's allegations fail to promote any inference of scienter based on motive.

2. The CAC Does Not Allege "Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness"

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious misbehavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." *Kalnit*, 264 F.3d at 139; *see also MRU Holdings*, 769 F. Supp. 2d at 515 (holding that increasing holdings during the class period is inconsistent with "strong circumstantial evidence of conscious misbehavior or recklessness"). When proceeding under this theory, a plaintiff must allege "conduct which is highly unreasonable and which represents an ***extreme departure from the standards of ordinary care*** . . . ." *Kalnit*, 264 F.3d at 142 (citations omitted) (emphasis added).

Here, the CAC must allege with particularity that each defendant engaged in such an "extreme departure" from ordinary care that it can be concluded they acted deceptively by knowing or suspecting in advance that the Phase III trial would fail. The CAC loosely attempts to meet this scienter standard by relying on CW statements and a "core operations" theory, but it fails to establish any inference that defendants knowingly or recklessly engaged in fraud.

a. The "CW" Statements Do Not Support the CAC's Scienter Allegations

Plaintiffs attempt to scrape together an inference of scienter from three CWs. This Court has held that CW allegations "must be discounted." *MRU Holdings*, 769 F. Supp. 2d at 516 (citations omitted); *see also Campo v. Sears Holdings Corp.*, 371 Fed. App'x 212, 216 n.4 (2d Cir. 2010) ("The anonymity of the sources of plaintiffs' factual allegations concerning scienter frustrates the requirement, announced in *Tellabs*, that a court weigh competing inferences . . . .").[9] The scant remarks attributed to these three CWs do not even hint at scienter.

CW1: CW1 is the former Chief Medical Officer of Ventrus and worked in that capacity from June 2007 until March 2009, ending his employment some twenty-one months ***before*** the Class Period began.[10] (CAC, ¶ 3.) CW1's claim that he worked with Dr. Ellison during his time at Ventrus is belied by the CAC. (*Compare id. with id.* at ¶ 29 (alleging Dr. Ellison's consulting relationship with Ventrus began in July 2010.) *See Const. Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008 WL 4370010, at *4 (S.D. Cal. Sept. 23, 2008) (discounting uncorroborated CW allegations). CW1 offers only his opinions – *not facts* – that (1) "there were not many patients" in the Phase IIb trial, and (2) "SPAs give investors the false

[9] Moreover, CWs must be described with sufficient particularity "to support the probability that a person in the position occupied by the source would possess the information alleged." *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000).

[10] CW1's allegations relating to events that took place after he left Ventrus must be disregarded. *See, e.g.*, *In re Downey Sec. Litig.*, 2009 WL 2767670, at *10 (C.D. Cal. Aug. 21, 2009).

impression that the FDA will likely approve the drug . . . ." (CAC, ¶¶ 13-14.) Plaintiffs must rely on facts, not opinions or conclusions, when utilizing CWs. *See In re Hypercom Corp. Sec. Litig.*, 2006 WL 1836181, at *6-7 (D. Ariz. Jul. 5, 2006); *accord In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008) ("Plaintiffs allege no facts indicating that [the CW] was qualified to make this or any medical diagnosis.").

More importantly, CW1's opinions are not connected to any conversation with Dr. Ellison or Mr. Barrett. There is no allegation that CW1 discussed such topics with either of them, or that they said anything to CW1 to indicate they were engaged in deception. *See In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 352 (S.D.N.Y. 2011) ("The absence of such [direct] communication undermines the inference that Defendants recklessly disregarded the truth."); *In re PXRE Group, Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 538 (S.D.N.Y. 2009) ("Plaintiff points to no case in which a court in this district has inferred a 'top executive's' 'access' to contrary facts based on the expression of 'concerns' from one employee to another . . . ."). In any event, CW1's opinion that SPAs tend to mislead investors is tantamount to saying that any company that fails to obtain drug approval after participating in an SPA process is engaged in fraud. Such a general allegation, not linked in any concrete way to particular statements or practices at Ventrus, is insufficient to promote an inference of scienter.

CW2: CW2 is thrice removed from Ventrus – he was an employee of a contractor hired by one of many third-party CROs that worked on the Phase III trial. (CAC, ¶¶ 4, 103.) The CAC does not allege that CW2 spoke with anyone at Ventrus, rendering his opinions about the way Ventrus conducted the Phase III trial irrelevant. (*Id.* at ¶¶ 18, 20.) *Wachovia*, 753 F. Supp. 2d at 352; *Novak*, 216 F.3d at 314. CW2's chief allegation – that Ventrus refused to pay for the removal of polyps in certain patients (CAC, ¶ 18) – has absolutely nothing to do with whether

VEN 309 had meaningful prospects as a treatment for hemorrhoids. Similarly, no inference of scienter can be drawn from CW2's alleged statement that Ventrus abruptly discontinued its VEN 309 program without "wait[ing] to analyze the results" of its Phase III trial (*id.* at ¶ 88); it is undisputed that Ventrus analyzed the Phase III trial results and disclosed that the trial failed to meet its primary and secondary efficacy endpoints, rendering any further analysis immaterial (*id.* at ¶ 90).

CW3: CW3 was an intern for the co-lead underwriter on the Ventrus IPO who had no involvement in the VEN 309 program and is not alleged to have spoken with anyone at Ventrus. (CAC, ¶¶ 5, 11.) His sole allegation is that a Ventrus shareholder made a presentation to National Securities and discussed VEN 309. (*Id.* at ¶ 11.) Not only is this allegation irrelevant, it is meaningless for the purposes of the scienter analysis. *See In re Zumiez Inc. Sec. Litig.*, 2009 WL 901934, at *8 (W.D. Wash. Mar. 30, 2009) (plaintiff did not provide "any facts to suggest that [CWs] were positioned to accurately assess the Company's performance on [ ] a broad scale").

b. The CAC's Remaining Allegations Do Not Show Scienter

When proceeding on a "conscious misbehavior" theory of scienter, a complaint must allege with particularity either that a defendant "knew facts or had access to information suggesting that their public statements were not accurate" or that he or she "failed to check information they had a duty to monitor." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.*, 531 F.3d 190, 194 (2d Cir. 2008) (quoting *Novak*, 216 F.3d at 311). Further, "[w]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Novak*, 216 F.3d at 309.

Here, the CAC identifies no document or record of any kind containing facts contrary to defendants' public statements, or putting defendants on notice that their public statements might be inaccurate. The CAC does not refer to a single conversation within Ventrus in which any doubts or disputes were raised, nor does it allege that any unfavorable comments were made by the FDA or by any other external source. *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) ("[T]here is nothing what[so]ever to indicate that the statements made did not reflect the honest belief of the authors.").

To the contrary, the undisputed facts compel the inference that it was reasonable for defendants to be optimistic about the VEN 309 clinical trial program. First, the FDA authorized Ventrus to proceed with the Phase III trial after reviewing all prior VEN 309 clinical trial results, including the Phase IIb trial, as part of the "end-of-Phase II" meeting. (*See* Exh. A at 6.) *See* 21 C.F.R. § 312.47(b)(1)(iv) (requiring sponsor to submit summaries of Phase I and II trials before meeting). Second, a *post hoc* analysis of the Phase IIb trial results examining the ***same endpoints*** as those in the Phase III trial showed highly statistically significant results in favor of VEN 309. (*See* CAC, ¶ 75; Exhs. A at 6, E at 112.) *Cf. Kleinman*, 706 F.3d at 154-55 (finding that a post-hoc analysis "deviate[ng] from the established protocol" did not support a fraud claim). Finally, any speculation that defendants knew about the Phase III trial results ahead of time is attenuated by the CAC's own allegation that "[a]ll clinical trials for VEN[ ]309 were performed by contract research organizations" (CAC, ¶ 103) – *i.e.*, Dr. Ellison and Mr. Barrett, like all Ventrus shareholders, had to wait to see how the Phase III trial results turned out.[11]

Having failed to marshal any genuine indicia of scienter, the CAC falls back on a so-called "core operations" hypothesis, alleging that scienter can be inferred merely on the basis of

[11] *Accord Shields v. Citytrust Bancorp.*, 25 F.3d 1124, 1130 (2d Cir. 1994) ("It is hard to see what benefits accrue from a short respite from an inevitable day of reckoning.").

VEN 309's "lead product" status and the high-ranking positions the individual defendants held at Ventrus. (*See* CAC, ¶¶ 104-106.) However, "this Court has carefully considered the continued viability of the 'core operations' inference in light of the PSLRA's heightened pleading requirement and found it lacking." *Shemian v. Research in Motion Ltd.*, 2013 WL 1285779, at *18 (S.D.N.Y. Mar. 29, 2013) (citing additional cases).

When viewed "holistically" (*Tellabs*, 551 U.S. at 326), the only reasonable inference to be drawn from the facts alleged, the documents incorporated into the CAC, and materials subject to judicial notice is that defendants believed their statements about VEN 309 to be true and had reason to be optimistic about the Phase III clinical trial. Given plaintiffs' failure to adequately allege scienter, the CAC must be dismissed.

B. The CAC Fails to Allege False Statements

The CAC must identify the specific statements that were false (or rendered misleading by an omission), and "must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). The CAC fails to meet this requirement.

1. Plaintiff's "Block Quote" Pleading Style Fails to Identify a Specific False Statement

The CAC's approach to pleading false statements is to "block quote" several of Ventrus' public disclosures without identifying the allegedly false portions of these quotations.[12] These block quotes are then followed by "generalized explanations of how the statements were false or misleading." *Toabor v. Bodisen Biotech, Inc.*, 579 F. Supp. 2d 438, 452-53 (S.D.N.Y. 2008). This approach, which does not tether the specific false statements to the specific reasons why each statement was false when made, does not satisfy Rule 9(b) or the PSLRA. *See id.* at 453

[12] Indeed, many of the statements in these block quotes – and even those highlighted by plaintiffs themselves – are objectively true. (*Compare* CAC, ¶ 40 (noting that Amer "had developed VEN 309 through Phase II studies . . .") *with* Exh. A at 6; *see also* CAC at ¶¶ 38, 42, 44, 57, 73, *etc.*)

(dismissing complaint using "block quote" approach); *In re Rigel Pharms., Inc. Sec. Litig.*, 2009 WL 5125344, at *8 (N.D. Cal. Dec. 21, 2009) (holding that complaint's block-quoted public statements – including some that were demonstrably true – failed to adequately identify a false statement or omission). As shown above, the gravamen of the CAC fails as a matter of law, but the inappropriate use of block quotes provides an additional reason for dismissal. The CAC should be dismissed with prejudice.

2. The Challenged Statements Were Not False

The CAC relies on three categories of misrepresentations or omissions that allegedly render defendants' statements about VEN 309 false: (1) the small sample size of the Phase IIb trial; (2) Ventrus' negotiations with the FDA concerning an SPA for the Phase III trial; and (3) updates regarding the Phase III trial's progress. Upon inspection of the documents quoted in the CAC, however, it is apparent that any alleged "omissions" were fully disclosed to the investing public and any alleged misstatements are based on gross mischaracterizations of the referenced documents. What's more, the CAC's challenged statements are demonstrably true or are non-actionable expressions of corporate optimism, and all statements are forward-looking and fall within the PSLRA's safe harbor.

a. Statements Regarding the Sample Size of the Phase IIb Study

The CAC does not contest that the results of the Phase IIb trial were accurately reported in Ventrus' SEC filings, or that the Phase IIb trial successfully met all efficacy endpoints, including the same endpoints that were the subject of the Phase III trial. (CAC, ¶¶ 36, 73, 75, 81, *etc.*) Instead, plaintiffs contend that it was misleading to tout these results because "[o]nly 121 patients were studied," purportedly making the Phase IIb study an unreliable gauge of future performance. (*Id.* at ¶ 13.) This argument fails for several reasons.

Most importantly, defendants repeatedly disclosed the 121-patient sample size of the Phase IIb trial. (*See* Exhs. A at 6, C at 53, D at 103, E at 112, *etc*.) *See MRU Holdings*, 769 F. Supp. 2d at 513 ("A complaint fails to state a 10(b) claim when the alleged omission has actually been disclosed.") (citation omitted). Moreover, as noted above, there is no suggestion that the FDA (or anyone else) took issue with the sample size of the Phase IIb trial when it authorized Ventrus to proceed with the Phase III trial program.[13] *Cf.* 21 C.F.R. § 312.21(b) (prescribing that Phase II studies should include "no more than several hundred subjects"). Lastly, the question of sample size is fundamentally a matter of scientific methodology, not a matter of fraud, especially since the Phase IIb sample size was fully disclosed. The Second Circuit has resoundingly concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors. *Klienman*, 706 F.3d at 153-55; *Abely*, 2013 WL 2399869, at *9-10 ("[P]laintiff's critiques all go toward the design of the study and not to the existence of actionable misrepresentations or omissions."). Other circuits agree. *See, e.g.*, *Rigel*, 697 F.3d at 879 (a complaint that "criticizes only" a study's methodology does "not adequately plead falsity").

b. Statements Regarding an SPA for the Phase III Study

The CAC claims that Ventrus' public statements about a possible SPA were false because (1) Ventrus ultimately chose not to formally obtain an SPA (CAC, ¶¶ 14, 60), and (2) Dr. Ellison described the negotiations with the FDA as "productive" (*id.* at ¶¶ 55-56). These allegations are insufficient to establish a false statement.

[13] Even if the sample size for the Phase IIb could be considered "small," "[i]f the assumptions underlying the statistical analysis are justified . . . then confidence intervals and test statistics are no less trustworthy than those for large samples." *See* Fed. Judicial Center, *Reference Manual on Scientific Evidence*, 126 n.145 (2d ed. 2000) ("Analyzing data from small samples may require more stringent assumptions, but there is no fundamental difference in the meaning of confidence intervals and p-values.").

First, the CAC points to no document, record or conversation to indicate that, at the time Ventrus announced that it was pursuing an SPA, it did not have a genuine intent to obtain one. Although Ventrus subsequently determined that it had sufficient guidance from the FDA to forego formal completion of the SPA process, this does not render its prior statements about its discussions with the FDA false. Indeed, it is undisputed that because Ventrus adopted the FDA's proposed changes to the Phase III trial protocol (CAC, ¶55), an SPA would have unnecessarily delayed the start of the Phase III trial (*id.* at ¶¶ 59, 61; Exh. F at 124). Moreover, the failure of the Phase III trial had nothing to do with the agreed-upon protocol: it resulted from the VEN 309 not meeting its efficacy endpoints despite earlier, promising results.[14]

Second, the CAC points to no document, record or conversation to indicate that Dr. Ellison's statements characterizing discussions with the FDA as "productive" were false when made. This is not surprising, since those discussions with the FDA resulted in the adoption of the same endpoints for the Phase III trial that were the subject of a *post hoc* analysis of the Phase IIb data which had yielded highly favorable results. (CAC at ¶ 75; Exh. E at 112) Nothing in the CAC suggests that Dr. Ellison did not have a good faith belief that VEN 309 had a reasonable prospect of satisfying the same endpoints in its Phase III trial.[15]

c. Statements Regarding the Phase III Study Progress

Using 20-20 hindsight, the CAC alleges that Dr. Ellison's statement in November 2011 that the VEN 309 Phase III trial was "progressing well with respect to data quality and GCRP

[14] The FDA's guidance makes clear that no reasonable investor could believe that an SPA for the Phase III trial would be indicative of FDA approval. *See Berry v. Valence Tech., Inc.*, 175 F.3d 699, 703 n.4 (9th Cir. 1999) ("A reasonable investor is presumed to have information available in the public domain . . . .") (citation omitted).

[15] Moreover, the Phase III trial was not less "subjective" than the Phase IIb trial. (CAC, ¶ 99.) To the contrary, both the Phase IIb and Phase III trials were based on patient-reported outcomes. (*Compare* Exh. A at 26 ("Daily patient diaries for bleeding, itching and pain/discomfort were recorded for 14 days, and patient assessments were recorded at days 7 and 14 based on a 10-point scale") *with* Exh. H at 134 (results obtained via "Symptom Satisfaction Questionnaire").)

(Good Clinical Research Practices)" was false because the trial ultimately did not meet its endpoints. (CAC, ¶¶ 69-70; *see also id.* at ¶ 67.) This allegation has no merit. The issue of "data quality" has nothing to do with whether a drug candidate will meet its endpoints – it concerns the integrity of the underlying data. Indeed, Dr. Ellison's statement was not a prediction of the results of the Phase III trial; rather, he was referring to Ventrus' ongoing monitoring of its CROs to "identify and follow-up on missing data, inconsistent data, data outliers, and potential protocol derivations that may be indicative of systemic or significant errors in data collection and reporting at a site." (Exh. J at 156; *see also* Exh. K at 171 (Dr. Ellison noting that "we have a minimal loss of key outcome data, which is very important in symptomatic studies . . .").) *See Abely*, 2013 WL 2399869, at *15-16 (statement that company was "very pleased with the Phase III progress we're seeing now" was not actionable).

Similarly, the CAC wrongly attributes fraud to Dr. Ellison's statement in November 2011 that "no serious severe adverse events related to the drug have been seen to date." (CAC, ¶ 68.) According to the CAC, this statement was false because "the drug's total ineffectiveness was a severely adverse event relating to the drug's chances of FDA approval." (*Id.*) But when Dr. Ellison used the term "severe adverse events," he was using a well-known industry term referring to whether the drug had caused death, injury or other toxic effects. *See* 21 C.F.R. § 312.32(a) (defining adverse event as "severe" if it involves "[d]eath, a life-threatening adverse event, [or] inpatient hospitalization . . ."). His comment concerned patient safety, not the chances of obtaining FDA approval. The CAC's twisted reading of Dr. Ellison's statement shows how far plaintiffs must stretch in attempting to plead a theory of fraud.

Finally, the CAC contends that defendants failed to disclose the reason why Ventrus delayed reporting the Phase III results until the second quarter of 2012. (CAC, ¶ 70.) Based on

rank speculation, the CAC asserts that the delay was "to effectuate a third offering of stock." (*Id.*) Tellingly, the CAC omits Dr. Ellison's discussion of the actual reason for the delay:

> [W]e now see enrollment being complete in April 2012, with the double-blind data . . . being available around June 2012. This change in guidance is due to a screen failure rate that was higher than expected. This was partially due to the need for having symptoms [two] days consecutively . . . And we're finding out that two consecutive days, actually people have to have pretty meaningful disease, which is actually what we want. And the other part is that these exclusion criteria that we've put in . . . for this study have knocked out a fair number of patients.

(Exh. K at 171.) The CAC does not attempt to challenge this perfectly legitimate reason for the brief 3-month delay.[16]

3. "Puffery" and Statements of Corporate Optimism Are Not Actionable

Plaintiffs challenge defendants' optimistic opinions about VEN 309's clinical trial program. (*See, e.g.*, CAC ¶ 38 ("VEN 309 demonstrated ***good*** tolerability . . ."), ¶ 55 (noting that FDA discussions were "***very productive*** . . ."), ¶ 69.) This challenge fails because "words like 'encouraging' are the type of 'expressions of puffery and corporate optimism' that do not generally 'give rise to securities violations.'" *See Kleinman*, 706 F.3d at 153 (quoting *Rombach*, 355 F.3d at 174); *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012) (holding that statements regarding a drug's "excellent" and "compelling" safety and efficacy profile were inactionable corporate optimism).

Moreover, defendants' optimistic opinions about the VEN 309 program cannot support fraud claims, particularly where they are meaningfully qualified:

- "[The Company is] *very pleased* with the new endpoint definitions in that they showed considerable differences between active drug and placebo in our analysis of

[16] A delay in reporting trial results is insufficient to demonstrate that Ventrus' prior guidance was false. *See Abely*, 2013 WL 2399869, at *16 ("Plaintiff does not allege that defendants invited any particular conclusions that should be drawn from the timing of the results' release. He therefore fails to allege that disclosure was required to render a past statement not misleading.").

an earlier Phase IIb study in Germany, which has been the cornerstone of our development program . . . *we believe* that the new endpoint definitions *have the potential* to provide a much stronger label . . . ." (CAC, ¶ 48 (emphasis modified));

- "Given what we have discovered about the commercial potential of VEN 309 . . . *we believe* that this *could considerably enhance* the value of the asset to the company." (*Id.* at ¶ 71 (emphasis modified.).

(*See* Section IV.B.4., *infra*, describing additional meaningful qualifications.) Such subjective statements can be actionable only if the "defendant's opinions were both false and not honestly believed when they were made." *Kleinman*, 706 F.3d at 153. As noted above, the CAC offers no particularized facts suggesting that defendants' statements were not honestly believed. *See In re Sierra Wireless Sec. Litig.*, 482 F. Supp. 2d 365, 367 (S.D.N.Y. 2007) ("The securities laws neither require corporate officers to adopt a crabbed, defeatist view of the company's business prospects nor permit dissatisfied shareholders to assert serious allegations of fraud based on the perfect hindsight afforded by the passage of time.").

4. Defendants' Forward-Looking Statements Are Protected by the PSLRA's Safe Harbor

The PSLRA protects a forward-looking statement where: (1) the statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) "plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(A)(i) & (B)(i). Further, as a matter of law, the assumptions underlying forward-looking statements are also protected. 15 U.S.C. § 78u-5(i)(1)(D). The first prong of the safe harbor is objective – *i.e.*, "meaningful" and "important" describe the cautionary statements themselves, not the speaker's or audience's view of them. *See In re Gilat Satellite Networks, Ltd.*, 2005 WL 2277476, at *12 (E.D.N.Y. Sept. 19, 2005); *Harris v. IVAX Corp.*, 182 F.3d 799,

803 (11th Cir. 1999).

The Challenged Statements Were Forward-Looking: Defendants' statements about VEN 309 and the drug's prospects for FDA approval were inherently forward-looking and fall squarely under the safe harbor. (*See, e.g.*, CAC, ¶ 63 ("***Depending on*** our assessment of the data generated by the Phase III trial . . . ***we intend to initial and conduct*** [additional studies] . . . ."); *id* at ¶ 87 ("***assuming positive data*** from the initial Phase III trial for VEN 309, ***conduct an additional pivotal Phase III trial*** . . ."") (emphasis modified).) 15 U.S.C. § 78u-5(i)(1)(A)-(D). In fact, fairly read (and of particular interest to shareholders), all statements in the CAC tie directly to VEN 309's FDA approval prospects. *Noble Asset Mgmt. v. Allos Therapeutics*, 2005 WL 4161977, at *9 (D. Colo. Oct. 20, 2005) (statements about FDA approval prospects were not actionable). The statements identified in the CAC regarding VEN 309's prior clinical trials only provided the basis for defendants' forward-looking optimism about FDA approval. *See In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 931-32 (9th Cir. 1996) (the statement that the "[the drug] significantly reduced the risk of stroke compared to aspirin" was an inactionable forecast in context of a pending NDA); *In re Columbia Labs., Inc. Sec. Litig.*, 144 F. Supp. 2d. 1362, 1368 (S.D. Fla. 2001) ("[S]tatements . . . touting [the drug's] possible effectiveness and promoting its marketability clearly constitute forward-looking statements . . . .").

Defendants Provided Meaningful Risk Warnings: All Ventrus press releases and the conference call transcript cited in the CAC contained meaningful warnings that "the results of clinical trials or preclinical trials may not be predictive of future results" and that Ventrus may not "receive regulatory approval for its drug candidates." (*See, e.g.*, CAC, ¶ 48; Exh. L at 188; *see also* CAC, ¶¶ 50, 55, 65, 67, 69, 73; Exhs. B at 36, E at 113, G at 132, K at 169, M at 194, Q at 242.) Moreover, each Ventrus press release and the conference call transcript expressly

referred investors and analysts to the extensive and meaningful risk factors in Ventrus' SEC filings. *See* 15 U.S.C. § 78u-5(c)(1) (permitting oral statements to incorporate risk factors by reference).

Ventrus' SEC filings cited in the CAC are replete with non-boilerplate risk factors addressing "to the letter" what ultimately happened: (1) "[O]ur research and development efforts might not result in any commercially viable products;" (2) "We have modeled the potential performance of the endpoints suggested by the FDA for our Phase III trial for VEN 309 using data from a prior double-blind Phase IIb trial of VEN 309 . . . While we believe th[e] post hoc analysis provided illustrative information . . . the successful results in the prior study might not be an indicator of success in our Phase III trials;" (3) "The commencement and rate of completion of clinical trials might be delayed by many factors, including, for example . . . slower than expected rates of patient recruitment;" and (4) "[t]he failure of clinical trials . . . could cause us to abandon a product candidate." (*See, e.g.*, Exhs. A at 10, 13-14, C at 62, 65, N at 218, T at 270, *etc*.)

Where "the important factors identified in conjunction with the forward-looking statement are precisely those that the plaintiff contends caused the actual results to differ materially, it is difficult to see how the cautionary language could be inadequate." *In re Thoratec Corp. Sec. Litig.*, 2006 WL 1305226, at *6 (N.D. Cal. May 11, 2006). Therefore, Ventrus' extensive risk warnings render the statements identified in the CAC inactionable as a matter of law under the PSLRA safe-harbor. *See MRU Holdings*, 769 F. Supp. 2d at 510 (rendering inactionable disclosures that, "[w]hen read in their entirety, . . . not only bespeak

caution, [but] shout it from the rooftops") (citation omitted).[17]

V. PLAINTIFFS' SECTION 20(A) CLAIM MUST BE DISMISSED

To state a claim for "control person" liability under Section 20(a) of the Exchange Act, plaintiffs must allege "a primary violation [of the Act] by a control[ ] person." *Slayton*, 604 F.3d at 777-78 (internal quotation omitted). Because plaintiffs fail to plead a primary violation of Section 10(b), plaintiffs' Section 20(a) claim must also fail. *Id.*

VI. CONCLUSION

For the reasons set forth herein, plaintiffs have failed to allege both that defendants acted with the requisite scienter and that defendants made any actionable false and misleading statements. For these two independent reasons, defendants respectfully request that the Court dismiss claims against them. Further, in light of the Court's statements at the pre-motion conference held on October 21, 2013, the CAC should be dismissed with prejudice.

Dated: November 22, 2013

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[17] Given the complete absence of facts showing scienter in the CAC (*see* Section IV.A., *supra*), plaintiff cannot demonstrate "actual knowledge by [the speaker] that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B). Therefore, the second prong of the PSLRA safe harbor also applies.